REMARKS

Applicant respectfully requests entry of the above amendments. Claims 1-30 are pending in this application. Claims 11, 13-16, and 19 are currently amended, claims 29-30 are new, and claims 1-10, 12, 17-18, and 20-28 are canceled. No new matter was added.

Claim Rejections and Subsequent Responses

35 USC §112 (1st Paragraph)

The Office Action rejected Claims 11-27 as failing to comply with the enablement requirement. The action indicated that the breadth of the claims was overly broad for claiming the prevention and prophylactic use of NK-1 receptor antagonists for a disease. Applicant has amended the claims accordingly so as to claim a specific NK-1 antagonist, e.g., that of Formula (1a). The compound of Formula (1a) is a marketed product, Cerenia. Applicant has included a press release (attached, and can also be found at: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01573.html) from the U.S. Food and Drug Administration announcing the approval of Cerenia for the prevention and treatment of vomiting. Therefore, based on the amendment, the rejection is deemed moot as a skilled artisan could easily assess the utility of the invention, and use it accordingly without undue experimentation. Applicant respectfully requests that said rejection be withdrawn.

35 USC §112 (2nd Paragraph)

Claims 12-27 were rejected for being indefinite because of insufficient antecedent basis and improper dependency. Claim 12 depended from claim 1 which was previously canceled. Claim 12 is now canceled. Claim 14 depended from claim 12. Claim 14 was amended to ensure proper dependency. Claim 17, which depended from claim 15, was construed as confusing because it claimed unsequestered meta-cresol in an amount which appeared to be greater than the claim from which it depended. To progress prosecution, Claim 17 was canceled. Claim 21 was rejected for clarity. Claim 21 was also canceled. Claims 13-16, 18-20, and 22-27 were rejected because they depended from the earlier rejected claims. Applicant amended claims 13-16, and 19 to ensure proper dependency and canceled claims 18, 20, and 22-27. Therefore, the rejection is deemed moot and Applicant

respectfully requests that said rejection be withdrawn.

Rejection based on 35 USC § 101

Claim 21 was rejected because it allegedly embraced two different statutory classes of invention, e.g., process of use and process of making. Claim 21 was canceled. Therefore, the rejection is deemed moot and Applicant respectfully requests that said rejection be withdrawn.

Rejection based on 35 USC §102

Claim 11 was rejected, §102(e), as allegedly being anticipated by Giles-Komar. To the extent that the rejection is applicable to the amended claim, Applicants respectfully traverse the rejection. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131. According to In re Bond, 910 F.2d 831,832 (Fed Cir. 1990), anticipation under 35 USC §102 requires that "every element of the claimed invention be identically shown in a single reference." More recently, the CAFC (2007-1565, October 20, 2008) in Net MoneyIn vs. Verisign and EProcessing Network, held that "unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 USC §102".

Giles-Komar teaches a pharmaceutical composition comprising a therapeutically active agent (anti-integrin antibodies), a beta-cyclodextrin, and other pharmaceutical excipients or additives, including a preservative (m-cresol). In contrast, the amended claim recites a composition comprising a compound of Formula (1a). Therefore, Giles-Komar fails to teach the specific composition claimed in the instant invention and therefore cannot anticipate the amended claim. The rejection is deemed moot and Applicant respectfully requests that the rejection be withdrawn.

Claims 12-14 and 20-24 were rejected, §102(e), as allegedly being anticipated by Bronk. Bronk teaches the method of using a compound of Formula (1a) for the treatment of abnormal anxiety behavior. As discussed above, a claim is anticipated only if each and

every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The claims, as amended, recite a pharmaceutical composition that is both injection site tolerant and has antimicrobial effectiveness. The current invention provides a parenteral formulation where cyclodextrin complexes with both the active ingredient and the preservative. In contrast, Bronk only recites a parenteral solution comprising either sesame or peanut oil or an aqueous propylene glycol solution. Therefore, Bronk does not anticipate the amended claims. Further, claims 12, and 20-24 were canceled. The rejection is deemed moot and Applicant respectfully requests that the rejection be withdrawn.

CFR 1.56 Obligation

Applicant for the instant invention (10/588,070) is Pfizer Products Inc. Applicant for the cited reference, Bronk (US 2003/0139443), is Pfizer Inc. Pfizer Products Inc. is a wholly owned subsidiary of Pfizer, Inc. Therefore, the instant invention and the invention claimed in the cited publication, Bronk, are in fact commonly owned.

Rejections based on §103

Claims 15-19 and 25-27 were rejected under 35 USC §103(a) as being unpatentable over Giles-Komar in view of Bronk, and as applied to claims 11-14 and 20-24, further in view of Ono. Claims 12, 17-18 and 20-27 were canceled. Claims 11, 13-16, and 19 were amended.

Giles-Komar recites isolated human anti-integrin α-V subunit antibodies, immunoglobulins, and cleavage products, compositions thereof, for the treatment of cell adhesion diseases involving α-V integrin mediated angiogensis, e.g., prostate, colon, and renal carcinoma. Compositions include an integrin molecule and a suitable carrier or diluent. The compositions recited provide for hundreds if not thousands of potential drug (integrin) compositions, excipients (including cyclodextrins), and/or preservatives. The citation does not provide any discussion relative to the complexation concerns relative to the use of cyclodextrins nor to the competitive inclusion complexation issues of a second compound, e.g., antimicrobial preservative. Therefore, a skilled artisan could not easily ascertain the composition of the instant invention without undue experimentation.

Bronk recites the use of NK-1 receptor antagonists, including the compound of Formula (1a), for the treatment of abnormal anxiety behavior in animals. The citation also recites a number of potential oral and parenteral formulations using basic pharmaceutical excipients. However, as stated above, the parenteral formulation only discloses the use of seasame or peanut oil or aqueous propylene glycol as excipients. There is no mention of preservatives, cyclodextrins, or more importantly the issues with drug-cyclodextrin-preservative complexation which can adversely affect drug efficacy, compositional microbial burden, or injection site toleration afforded by the pharmaceutical composition of the instant invention.

Ono recites complexation issues relative to the use of cyclodextrins, particularly as they relate to the solubility and permeation of phenacetin and various benzoic acids. Phenacetin and the benzoic acid derivatives were employed for modeling because they were known to form 1:1 inclusion complexes with β-cyclodextrins (pg 134, lines 26-29, left column), thereby making modeling assumptions more straight forward. Modeling requires the determination of stability- and permeation rate constants in free and complexed fractions. Per Ono, "the permeation rate of cyclodextrin complexes is significantly affected by the presence of second guest molecules, due to competitive inclusion" (page 137, Section 4.2, lines 1-3). Therefore, a skilled artisan could not presume complexation stoichiometry of any compound alone, or in combination with another competitor complexing agent. Therefore, based on the physicochemical and biological properties of a drug, competitive inclusion complexation of second guest molecules, stability constants, permeation rate constants, and unknown complexation stoichiometry of literally thousands of drugs, preservatives, excipients, and cyclodextrins, the skilled artisan would not be able to ascertain the pharmaceutical composition of the instant invention without undue experimentation.

As amended, Claim 11 recites a parenteral pharmaceutical composition which includes a β-cyclodextrin which complexes with the compound of Formula (1a) and the preservative in such a manner as to ensure drug efficacy, injection site toleration, and preservative effectiveness regardless of competitive inclusion complexation. Claims 13-16, and 19 were amended and depend from claim 11. In light of the aforementioned arguments, Applicant disagrees that it would be obvious for a skilled artisan to prepare a pharmaceutical composition, as claimed, in light of Giles-Komar, Bronk, and/or Ono. Therefore, the

rejection is deemed moot and Applicant respectfully requests that the rejection be withdrawn.

Conclusion

Applicant respectfully requests that this amendment be entered. Further, Applicant has responded to all points and concerns raised by the Office Action and respectfully requests that said rejections be withdrawn. Applicant believes the application is now in condition for allowance, and respectfully requests an early and favorable action. Applicant would like to take this opportunity to thank the Examiner of record for her assistance with the prosecution of the application.

Respectfully submitted,

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